K062205

FEB - 5 2007

X. 510(k) SUMMARY OF SAFTEY & EFFECTIVENESS

PROPREIETARY NAME:	DBX® Strip
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device
PRODUCT CODE:	87—Orthopedic Devices
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202

INDICATIONS FOR USE:

DBX® Strip is indicated as a bone void filler for treatment of surgically created osseous voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the pelvis, extremities, and the posterolateral spine for posterolateral fusion. DBX® Strip, when used for posterolateral spine fusion, may be used with autograft.

DBX® Strip is for single patient use only.

DEVICE DESCRIPTION:

DBX® Strip is a flat, malleable device composed of human demineralized bone matrix (DBM), sodium hyaluronate (NaHy), sodium phosphate dibasic buffer and gelatin (procine origin). DBX® Strip is for single patient use only and is available in five sizes.

SUBSTANTIAL EQUIVALENCE INFORMATION:

DBX® Strip was cleared by FDA (K042829) as a bone void filler for use in the posterolateral spine. The new DBX® Strip is substantially equivalent to DBX® Strip, FDA cleared K042829. The only modification is the expansion of the indications to include use of DBX® Strip in the pelvis and extremities.

SAFETY AND EFFECTIVENESS INFORMATION:

Biocompatibility of DBX® Strip materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. DBX® Strip is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVITY POTENTIAL:

DBX® Strip is osteoconductive, and has been shown to have osteoinductivity potential in an athymic mouse. Every lot of final product will be tested to ensure the osteoinductive potential of the final product. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses. The DBX® Strip process further reduces the risk of viral contamination beyond donor testing and screening procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2007

Musculoskeletal Transplant Foundation
c/o Ms. Nancy Bennewitz
Regulatory Affairs Submission Specialist
125 May Street
Edison, NJ 08837

Re: K062205
DBX® Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: November 10, 2006
Received: November 13, 2006

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

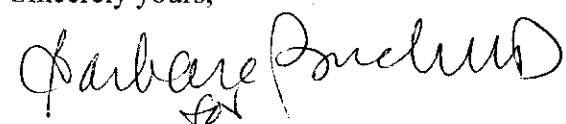
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE

510(k) Number (if known): K062205

Device Name: DBX® Strip

Indications for Use:

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DBX® Strip is for single patient use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062205